4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0636]

Global Unique Device Identification Database; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Global Unique Device Identification Database (GUDID)." FDA is issuing this draft guidance to communicate our current thinking of how the GUDID will operate. The guidance includes both information about how device labelers (in most instances, the device manufacturer) will interface with the GUDID, as well as information on the database elements that must be submitted to the GUDID and their definitions. We intend to publish a final guidance after the close of the comment period and our implementation of the GUDID.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Global Unique Device Identification Database (GUDID)" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm.

4613, Silver Spring, MD 20993-0002. Send a fax request to 301-847-8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jay Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3216, Silver Spring, MD 20993-0002, email: udi@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007, 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The unique device identification (UDI) system proposed rule was published on

July 10, 2012 (77 FR 40736), followed by an amendment modifying the implementation timeframe for certain devices, which was published on November 19, 2012 (77 FR 69393).

In developing the proposed rule, FDA solicited and considered input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives as possible were incorporated. The GUDID is a critical component of the UDI System. While the UDI assigned to each device is a globally unique, yet unintelligent code, the GUDID will house a uniform set of required attribute information, including the device identifier (DI) component of the UDI, for the devices reported to the GUDID. Being unique for each device, the DI component of the UDI can be effectively used by stakeholders to access the other GUDID attribute information for that device.

Labelers will be responsible for submitting information to the GUDID as part of their UDI requirements. This draft guidance document describes how labelers would obtain access to the GUDID, how to submit DI records to the GUDID, and how all stakeholders can search and retrieve device information. This draft guidance is being issued to provide general information about the GUDID.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the GUDID. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or at http://www.regulations.gov. To receive "Global Unique Device Identification Database (GUDID)," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1831 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's July 10, 2012, proposed rule on the UDI system (77 FR 40736), which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (77 FR 40736 at 40762) and has submitted them for OMB approval (OMB control number 0910-0720).

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: September 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-23058 Filed 09/20/2013 at 8:45 am; Publication Date: 09/24/2013]